

**BEFORE THE
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**

**COMMENTS OF THE
ROHM AND HAAS COMPANY**

**ON
EPA'S ESTABLISHMENT OF ELECTRONIC REPORTING: ELECTRONIC
RECORDS PROPOSED RULE**

Establishment of Electronic Reporting;
Electronic Records: Proposed Rule

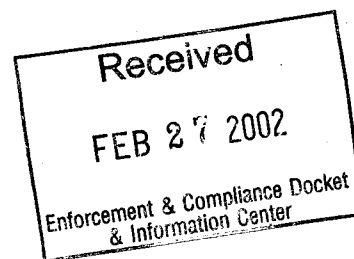
66 FR 46161 (August 31, 2001)

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February 27, 2002

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EXECUTIVE SUMMARY

Rohm and Haas Company is submitting these comments on EPA's proposed Cross-Media Electronic Reporting and Record-keeping "CROMERR" rule. 66 FR 46161. (August 31, 2001).

We appreciate the opportunity to comment on the EPA proposed rule on behalf of Rohm and Haas Company.

Rohm and Haas is a Philadelphia-based specialty chemical company which makes products for the personal care, grocery, home and construction markets, and the electronics industry. Today Rohm and Haas has sales of approximately \$6 billion and more than 17,000 employees. It operates nearly 140 research and manufacturing locations in 27 countries. The company has more than 100 ISO 9000 and more than 25 ISO 14000/EMAS registrations around the world. Rohm and Haas is committed to being a good neighbor and responsible corporate citizen. The company sponsors a number of initiatives, including Responsible Care®, Community Advisory Committees, and activities centered on the health and safety of employees, customers, the communities where we are located, and protecting the environment.

We have reviewed the EPA proposed rule, using an internal cross-functional team consisting of manufacturing, regulatory, research, and information technology professionals.

We agree that the move towards electronic reporting and submission of regulatory filings is a valuable goal. In addition, we agree that electronic record keeping may also reduce costs and improve efficiency. Rohm and Haas strongly supports EPA's stated goals of reducing the cost and burden associated with data transfer, improving data quality, speed, and convenience, and reducing the environmental and economic burden associated with large scale and long term maintenance of voluminous paper records. Upon review of the proposed rule, however, Rohm and Haas believes that the proposal fails to adequately account for the variety of existing electronic records systems and the costs associated with changing them to meet the requirements of this rule, the unintended mandatory and prescriptive nature of the requirements, and the need for flexibility to address the variety of regulatory requirements covered and to address future changes in technology.

After reviewing the proposed rule, Rohm and Haas has identified the following issues:

? The rule, as it is written, is not voluntary for our company, because we leverage the use of information technology for record-keeping and compliance management. A variety of existing systems are used to collect and manipulate data; substantial changes to hardware, software, and procedures for these systems could be required in order to continue to use this electronic data under the rule.

? Many of Rohm and Haas' computer systems would be impacted as there is pervasive use of systems in manufacturing, research and administrative facilities throughout the US.

? Our current systems would not meet the technical requirements as specified in the proposed rule.

- ? Costs associated with changing electronic systems to meet the requirements of the rule could be prohibitive; the result could be regression to paper record-keeping.
- ? There will be impact to third-parties that provide electronic data and records to our facilities, for example laboratories that provide sample analysis.
- ? There are many potential regulatory impacts; record-keeping provisions may conflict with existing rules.
- ? As drafted, record-keeping provision may actually impose additional requirements for records maintained; requirements for "audit trail" documentation may impose requirements to keep raw data, calculations, or other backup material not otherwise subject to record-keeping requirements.
- ? The proposal would impact today's work processes and procedures; procedures and practices for data collection, reporting, and record-keeping would have to be revised to address the new requirements.
- ? There are a variety of operational issues that will make compliance with this rule challenging and costly.
- ? Rohm and Haas estimates a high cost to meet the requirements of the proposed rules and high on-going costs to maintain compliance.
- ? EPA appears to have performed insufficient due-diligence with regards to cost-benefit analysis on the impacts of the proposed rule.

EPA should bifurcate this proposal into separate reporting and record-keeping components. Reporting may be addressed by creating effective and uniform systems for the regulated community to use in submitting standardized reports or forms. This is already authorized under various environmental programs without the benefit of a specific rule. EPA may expand electronic reporting through guidance or simply by making such reporting systems available to the regulated community.

The record-keeping component of the proposal should not progress without substantial rethinking by EPA. If EPA is compelled to develop recommendations on record-keeping, it should be in the form of guidelines on the use of computers to maintain records, not in the form of rule making. The existing proposal is not sufficiently flexible to cover all industries and regulatory programs addressed. It includes unintended expansions of the records that must be maintained. It does not adequately consider the costs associated with massive shifts to new technology, software, and procedures that may be required to comply with the rule. Although described as "voluntary," the proposal would require substantial changes in existing electronic data gathering and record-keeping. Finally, the proposal does not provide sufficient flexibility to allow the regulated community to adjust to improving information technologies.

EPA needs to give significantly more thought to flexibility and less on the need for "enforcement" driven purity of records and reports maintained on computers. In this instance, a one-size rule certainly does not fit all impacted industries, regulatory

programs, or state or local regulators.

Comments Section

We have reviewed the EPA proposed rule, using an internal cross-functional team consisting of manufacturing, regulatory, research, and information technology professionals.

After reviewing the proposed rule, Rohm and Haas provides the following comments:

General Comments

The rule, as it is written, is not voluntary for our company or for the chemical industry, because we leverage the use of information technology to stream-line the process of record creation, record-keeping, and reporting, where practical. In practice, manufacturing and research facilities located in the US have at least some portion of their environmental records and reports computerized for ease of data retrieval, retention, sharing and management.

Our current systems do not meet the technical requirements as specified in the rule's criteria for electronic systems – such as audit trail, etc. We do not believe that there are any systems that would be able to currently meet all of the requirements consistently for the life of many records that EPA requires facilities to meet. For instance BIF records must be maintained for the life of the facility. This could easily run 10, 15, 20 years or more. There are no computer systems (hardware or software) that we are aware of that have that sort of life expectancy. Thus, expecting a facility's computerized data system to produce records that are “accurate and complete copies of an electronic record and render these copies in both human readable and electronic form throughout the entire record retention policy” is an unrealistic expectation.

The proposal contains important improvements for industry and other stakeholders who must submit environmental data to EPA. The agency is attempting to streamline the reporting of information electronically rather than the continued submission of printed reports. The increased efficiencies of electronic submission of environmental data will save time and money for both the submitters and the agency. This part of the rule will allow time for submitters to migrate to electronic submission since they may continue to submit printed reports if they so choose.

Impacts Category

Many computer systems are impacted as there is pervasive use of systems in manufacturing facilities that collect, handle, and aggregate compliance data. Multiple systems exist at manufacturing and research sites. These range from a simple desk top machine connected to the company's main server system to complex integrated process control systems. We estimate that at least 75% of these computer systems would be impacted by this regulation.

There will be impact to third-parties that provide electronic data and records to our facilities as well as to our local regulatory agencies. Examples of third party data

providers are contract testing facilities under the National Environmental Laboratory Accreditation Conference and contract research organizations that develop GLP data under both FIFRA and TSCA. These groups should become engaged in discussions on the record-keeping and reporting provisions of the proposed rule. Additionally, there will be significant impact to our state and local regulators as they are the primary regulatory agency for many facilities. This means that each and every one of their systems will need to be upgraded to meet the proposed rule's requirements. EPA must make sure that their requirements are flexible enough to meet the diverse needs of these audiences as well as the regulated community.

The proposal would impact today's work processes and procedures. Each one of our facilities has current work processes and procedures in place. These include the basics of where environmental data are stored, up to and including validation of changes to hardware and software. EPA does not address the added cost of changing these processes and procedures in their proposed rule.

Cost / Scope Category

The scope of the record-keeping part of the rule is much broader than EPA originally thought. We estimate high costs to come into compliance with the requirements. These costs will include inventorying, assessment, remediation, validation, and certification of the all systems that maintain any environmentally related records.

On-going costs to maintain compliance will be significantly higher, due to the strict criteria being applied and we do not believe that EPA has adequately evaluated this on-going cost in their analysis.

If this proposal is finalized as drafted and the regulated community must immediately comply with all the requirements, including significant changes to hardware, software, and procedures, this will be an extreme hardship in terms of both human resources (IT and Environmental) and money. Therefore, EPA needs to include a time to transition to new systems, prepare new work processes and procedures. Rohm and Haas suggests that 3 or more years are needed to transition all impacted records and reporting processes.

Regulatory Impacts Category

Existing environmental regulations are amended by this rule. Our interpretation of the EPA's proposed rule would indicate that once an environmental record or report is in electronic format, a hard copy print out of the data is no longer sufficient to prove compliance with the regulatory requirement. This, in and of itself, is a new requirement that EPA is proposing. This requirement will significantly drive up the costs of the proposal. Most companies currently keep records electronically and will print out the copies of those same records in order to meet record retention requirements as computer systems become obsolete. Thus, current electronic record-keeping systems are declared impermissible. It is unreasonable to require electronic access to records that must be maintained for a long term. The rule must clarify that paper printouts of records originally recorded electronically are acceptable when the system becomes obsolete or is

updated with an incompatible technology. Moreover, for very long term records, paper copies may be the most durable method of storage.

The EPA GLP predicate rules (40 CFR §160 and 40 CFR §792) specify the development and maintenance of records in many sections. Presumably each of these GLP records would have to meet the requirements of section 3.100. EPA should clarify whether it intends to cover Electronic Records under the GLP regulations for data development.

The rule's prescriptive requirements regarding the level of detail required for authentication of records, audit trail, etc., conflict directly with EPA's efforts to apply the concept that "any credible evidence" may be used in connection with compliance certifications and other purposes. Data integrity and "credible evidence" should be parallel, so that data collected and maintained under the rule is sufficient to demonstrate compliance or non-compliance, and data that is unreliable or inadequate to meet the rule's requirements cannot be used for enforcement. EPA should consider linking these concepts, so that a reasonably reliable assurance of data quality should also form the basis for compliance determinations and certifications. The rule could be made sufficiently flexible to enable the regulated party to determine whether its data is reliable, knowing that it must use the data to prove compliance.

EPA should perform additional due-diligence. At a minimum, EPA should conduct a risk assessment / cost-benefit analysis on the need for anti-fraud provisions. Although some assurance of data integrity and protection from fraudulent use of electronic data or reports is warranted, EPA should not mandate in detail how to ensure this integrity. Regulating too specifically on this issue will not only require some regulated entities to abandon existing systems that may be perfectly adequate, but will also have the effect of limiting technological innovation in this area.

Operational Category

We need to have some period of time in which to retrieve the electronic records / documents for review. Voluminous records may not be able to be stored in the system, and may require transferal to electronic storage media.

Validation as we move data from system to system will be time-consuming and expensive. Validation of systems after routine upgrades will be burdensome. EPA should not mandate the extent and nature of validation, to allow the regulated community to assess its own systems, and to authorize the use of new, more efficient validation systems as they are developed.

Storage media obsolescence is an issue. We do not know how long storage media such as CDs or tapes will last. Replication to the next media can be time-consuming. Ensuring that the data integrity is maintained is burdensome and expensive. The proposal must be revised to clarify that paper copies of data stored on systems that are becoming obsolete is authorized.

Software application obsolescence is an issue. It is difficult to reconstruct applications

for long retention periods – coupled with retention of original technology, people with knowledge, etc.

We need to be able to rely on certification guidance provided by software vendors that their application is CROMERRR compliant. Then we need guidance on showing compliance of the end-to-end electronic record-keeping system. (i.e., integration of the vendor software into our environment). The proposal must clarify that the regulated community is entitled to rely on such certifications and integration by vendors.

The GLPs at 40 CFR §160 require the retention of records for the life of a FIFRA registration. This retention period could last many decades. Changes in media for retention of Electronic records will make frequent migration necessary. Retention of printed paper records are durable and should still be permitted in certain areas. Guidelines on acceptable preservation formats under various retention time-frames would be helpful.

The volume of data required for retention could be high. The volume of data coupled with the retention requirements and obsolescence constraints will be burdensome. Audit trails and fail-proof detection methods do not exist in today's current software systems.

Existing software systems lack the capability to perform many of the functions and sub-functions required for compliance with this proposal. Meta-data and the archiving of meta-data is not a pervasive capability in today's current software systems. Creating a repository of indexed, on-line and archived electronic records and retaining the ability to easily search and retrieve records is a challenge; existing systems will not comply with these aspects of the proposal.

A secure method of protecting critical business information is needed when conducting electronic reporting. National security issues as well as business confidentiality must be addressed in connection with electronic reporting.

The cost of electronic signatures are not trivial. Purchase of electronic certificates from the certificate authority for all of the approved signers across all of Rohm and Haas Company's North American facilities, and management of the certificates to create the PKI capability, is expensive and on-going. EPA has indicated awareness of this cost and their proposal to act as a certificate authority and/or minimize costs is welcomed.

Conclusion

Our Recommendation

Rohm and Haas recommends that the electronic record-keeping part of the rule be removed completely in order to achieve the EPA goal of making this a "voluntary" rule. As currently drafted, the rule has significant unintended consequences regarding existing data collection and record-keeping guidance. Because electronic record-keeping is currently widespread within industry, additional investigation is required before any

reasonable rule on electronic record-keeping can be created. Electronic reporting is a simpler issue, and may be accomplished promptly and without formal rulemaking.

We support the concept of voluntary electronic reporting. The increased efficiencies of electronic submission of environmental data will save time and money for both the regulated and the regulators. In fact, various state regulatory agencies are presently receiving electronic reports from industry, such as SARA 313, SARA 312, wastewater discharge monitoring reports, and hazardous waste information. These electronic reporting systems have been established without the need for mandatory or "voluntary" rule making. Nevertheless, Rohm and Haas questions the need for a rule around electronic reporting. EPA could expand the programs and reports subject to electronic reporting simply by making simple and easily used reporting systems, electronic forms, and other tools available to the regulated community. The regulated community will freely use a system that is more efficient and cost effective than preparing paper reports. If necessary, EPA could issue guidance on the use of such electronic reporting systems that would cover the issues raised in this proposal.

If the electronic record-keeping portion of this rule is made a stand-alone rule in the future, the EPA needs to fully evaluate the cost to meet the requirements as well as the costs to maintain on-going compliance. Any move toward a rule for electronic record-keeping must recognize the significant investment that industry has already made in electronic record-keeping systems by including a reasonable transition period to new systems. EPA needs to do additional evaluation of existing systems used for the collection, manipulation, and record-keeping of environmental data. Many of these systems are intimately linked to process control, and mandating the changes identified in the record-keeping portion of this proposal would have far-reaching unintended effects on operations and technology. In addition, EPA needs to perform cost/benefit analysis on the need for electronic manipulation of data that must be retained for decades. Retention of printed paper records (of electronically captured records) must continue to be permitted, at least until additional stakeholder input on electronic records and a proper cost impact analysis can be obtained. A risk assessment and cost/benefit analysis should also be performed in connection with data integrity and anti-fraud provisions, and any requirements must be sufficiently flexible to accommodate improvements and changes in technology. Finally, Rohm and Haas recommends that requirements for electronic record-keeping be performance-based guidance, instead of prescriptive criteria requirements.



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02/27/02 05:19 PM

To: docket.oeca@epamail.epa.gov
cc:
Subject: Comments on Docket No. EC-2000-007

Dear Sir or Madam:

Attached please find a copy of the comments of Rohm and Haas Company on the Proposed Rule - Establishment of Electronic Reporting; Electronic Records originally published in the Federal Register on Aug. 31, 2001 (66 Fed. Reg. 46162). The Docket number is EC-2000-007. An original and four copies have also been sent via First Class Mail.

Thank you for the opportunity to comment on this proposed rule.

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